

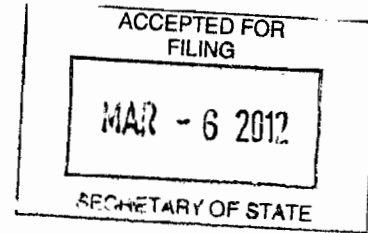
Rule-Making Cover Sheet

MAPA-1

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333.

2012-67

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. **Agency umbrella and unit number:** 02-392
(2 digit umbrella # and 3 digit unit #)
3. **Title of rule:** Automated Pharmacy Systems
4. **Chapter number assigned to the rule:** 20
(must be 3 digits or less)
5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, 10-12-11; mailing to interested parties, 09-29-11; posting on OPOR's web site, 09-28-11
6. **Date(s)/place(s) of hearing(s):** 11-03-11, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. **Type:** ☐ new rule ☐ partial amendment(s) of existing rule
☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule
☒ repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. **Name/phone of agency contact person:** Geraldine Betts, Board Administrator, (207) 624-8625

9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

- ☐ Provisional adoption (prior to Legislative review) ☐ Final adoption
☐ Emergency adoption of major-substantive rule

10. **Certification Statement:** I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on February 2, 2012.

Signature: _____

(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

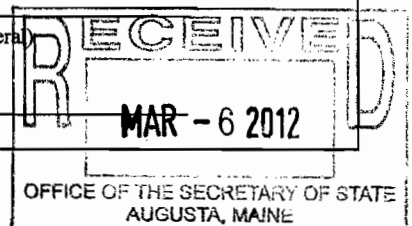
11. **Approved as to form and legality by the Attorney General on** _____

3/1/12
(date)

Signature: _____

(original signature, personally signed by an Assistant Attorney General)

Printed Name: Christopher W. Mann



EFFECTIVE DATE: MAR 11 2012

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 20: AUTOMATED PHARMACY SYSTEMS**

Summary: This chapter sets forth requirements for automated pharmacy systems.

SUBCHAPTER 1
(RETAIL PHARMACIES)

1. Scope

The provisions of this subchapter apply to automated pharmacy systems that are wholly located in a retail pharmacy.

2. General Use; Control by Pharmacist

An automated pharmacy system may be used for a patient profile dispensing system only if operation of the system is controlled by a pharmacist in all respects. For purposes of this chapter, such control includes but is not limited to the ability to fill prescription drug orders; control access to the machine; permit, block and monitor all stocking and dispensing activity; check inventory levels inside the machine; authenticate users of the system; authorize different levels of user access to the system; and deactivate or shut down the system.

3. Access to Automated Pharmacy System

Only a pharmacist, a pharmacy technician working under the direct supervision of a pharmacist as described in Chapter 1, Section 14(A) and Chapter 7, Section 4(3) of the board's rules, or a person legally qualified under a health practice act to administer drugs may stock, remove or label drugs from an automated pharmacy system. No person with access to an automated pharmacy system shall remove more drugs than necessary to fill a prescription.

4. Verification

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergies and drug interactions, prevent therapeutic duplication, and verify appropriate quantity and dosage. The pharmacist shall verify the order prior to dispensation of the drug to the patient or the patient's authorized representative.

5. Responsibilities of Pharmacist on Duty

The pharmacist on duty shall:

1. Directly supervise the stocking of previously packaged and labeled drug units into an automated pharmacy system; and
2. Directly supervise the removal of the drug from an automated pharmacy system and the final labeling of the drug after removal from an automated pharmacy system.

6. Physical Security; Unauthorized Access

A dispensing machine must be kept locked except when unlocking is necessary for loading or servicing. An automated pharmacy system must be electronically protected against unauthorized access, and must be constructed and installed in such manner as to prevent tampering, break-in and theft of inventory.

7. Training

All persons given access to an automated pharmacy system must be adequately trained in the operation of the system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

8. Development of Procedures

The pharmacist in charge shall develop, implement, and maintain procedures for the safe and effective use of medications dispensed via an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading and unloading of drugs, and records of the dispensing of drugs, are electronically tracked and recorded by the system and maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. The automated pharmacy system has a documented and ongoing quality assurance program that monitors total system performance;
4. Timely and documented maintenance is performed on the automated pharmacy system in accordance with the manufacturer's recommendations;
5. The purity, potency, and integrity of the drugs contained in the automated pharmacy system shall be preserved;

6. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules; and
7. In the event of a consumer-level recall, the pharmacist in charge can access records of all drugs that have been secured in the automated pharmacy system;
8. The pharmacist in charge develops and maintains a comprehensive backup strategy and disaster recovery plan for use in the event of a technical malfunction resulting from loss of power or internet connectivity or a system malfunction; and
9. Requirements for controlled substances security are met.

SUBCHAPTER 2

(INSTITUTIONAL PHARMACIES)

1. Scope.

The provisions of this subchapter apply to automated pharmacy systems that are located in a rural health center or free clinic; or in a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center (other than a licensed pharmacy), penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board.

2. General Use; Control by Pharmacist

An automated pharmacy system may be used for maintaining patient care unit medication inventories or for a patient profile dispensing system only if the system is under the supervision of a pharmacist in charge and is controlled by a pharmacist at all times. For purposes of this chapter, such control includes but is not limited to the ability to fill prescription drug orders; control access to the machine; permit, block and monitor all stocking and dispensing activity; check inventory levels inside the dispensing machine; authenticate users of the system; authorize different levels of user access to the system; and deactivate or shut down the system or a dispensing machine at a point of care location.

3. Remote Dispensing

An automated pharmacy system may dispense drugs at one or more point of care locations remote from the pharmacist in charge of the system or the pharmacist on duty. The pharmacist in charge and pharmacist on duty need not be physically present at the point of care location and need not be located within the State. However, such pharmacists must be licensed in Maine and must be in good standing with the board.

4. Access to Automated Pharmacy System

1. Health Care Professionals; Corrections Personnel

Only a pharmacist, allopathic physician, osteopathic physician, certified nurse practitioner, registered nurse, licensed practical nurse, physician's assistant, dentist, podiatrist, or appropriately-trained corrections personnel specifically designated by the warden, superintendent, director or chief administrative officer in charge of a penal institution may:

- A. Accept delivery of prescription medication to be loaded into a dispensing machine at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location; and
- D. Perform other functions related to an automated pharmacy system.

Except as set forth in subsection 2 below, none of the foregoing duties may be performed by a medical technician, medical assistant, certified nursing assistant, mental health rehabilitation technician or any other person whose profession or occupation is not listed in this subsection.

2. Pharmacy Technicians (advanced)

A pharmacy technician (advanced) working under the direct supervision of a pharmacist as defined in Chapter 1, Section 14(A), (B) or (C) of the board's rules and as referenced in Chapter 7, Section 7(1)(B) of the board's rules may:

- A. Accept delivery of prescription medication to be loaded into a dispensing machine at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location for quality assurance purposes or to carry out a change in formulary; and
- D. Perform other functions related to an automated pharmacy system except for the removal of drugs from a dispensing machine at a point of care location for purposes of administration or dispensing to patients.

No person with access to a dispensing machine may remove more drugs than necessary to fill a prescription or meet the immediate needs of a patient in a hospital or institution.

5. Verification of Prescription Medication to be Dispensed by an Automated Pharmacy System

An automated pharmacy system must use bar code scans or other technology to ensure that the prescription medication to be loaded into a dispensing machine at a point of care location is the intended drug in the intended strength, dosage form and quantity. The pharmacist in charge or pharmacist on duty shall verify that the canisters, pockets or containers to be inserted into the dispensing machine have been properly filled and labeled.

6. Transport and Delivery

Prescription medication to be dispensed by an automated pharmacy system must be transported by courier in locked, tamper-evident carriers to the point of care location for loading into a dispensing machine. The pharmacy or institution receiving the prescription medication shall maintain a delivery log showing the name of the sending pharmacy and pharmacist on duty, the name and employer of the courier, the date and time of delivery, the drugs delivered, and the name of the person accepting delivery on behalf of the pharmacy or institution.

7. Insertion of Canisters, Pockets or Containers into Dispensing Machine

A dispensing machine at a point of care location must use bar code scans or other technology to ensure that the contents of a canister, pocket or container are accurately recognized by the machine.

8. Dispensing of Drugs

A dispensing machine at a point of care location must dispense medications exactly in accordance with the prescriptions entered into the automated pharmacy system. A dispensing machine at a point of care location may only dispense patient-specific drugs to fill an immediate need.

9. Verification of Prescription Drug Order; No Final Check Required

1. Verification

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergies and drug interactions, prevent therapeutic duplication, and confirm appropriate quantity and dosage. The pharmacist shall verify the order as soon as practicable after administration of the drug to the patient or resident, but in no event more than 28 hours afterwards.

2. No Final Check

No final check on the filled prescription need be performed.

10. Security; Restricted Access

A dispensing machine at a point of care location must be kept locked except when unlocking is necessary for loading or servicing. The dispensing machine must be electronically protected against unauthorized access, and must be constructed and installed in such manner as to prevent tampering, break-in and theft of inventory.

11. Video Surveillance; 2-Way Communication; Availability of Pharmacist**1. Video Surveillance**

A dispensing machine at a point of care location must be under video surveillance by the pharmacist in charge or pharmacist on duty 24 hours per day, 7 days per week. Video surveillance consists of separate video cameras trained on the front face of the machine and all other sides of the machine that open for loading. The cameras must be set up so as to facilitate visual identification of persons who service, stock, log on to or remove product from the machine. The video cameras must continually transmit color images at a frame rate no less than 15 frames per second.

The board may grant a waiver from this requirement in whole or in part upon a showing that other security measures in place at the point of care location provide equivalent protection to the requirements of this subsection.

2. 2-Way Communication

There must also be a 2-way, real-time voice and video communication link in operation at all times (24/7) between the pharmacist in charge or pharmacist on duty and any person who services, stocks, logs on to or removes product from the machine.

3. Availability of Pharmacist

A pharmacist must be available by telephone at all times (24/7) to consult with a pharmacy technician (advanced) or person legally qualified under a health care act to administer drugs regarding any drug dispensed by an automated pharmacy system if a pharmacist is not available at the point of care location where the drug is dispensed.

12. Training

All persons given access to a dispensing machine at a point of care location must be adequately trained in the operation of the automated pharmacy system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

13. Development of Procedures

The pharmacist in charge shall develop, implement, maintain and follow procedures for the safe and effective use of drugs dispensed from an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading, unloading, and returning of canisters, and records of the dispensing of drugs, are electronically tracked and recorded by the system and are maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. Before an automated pharmacy system is deployed at a new point of care location, the pharmacist in charge has tested and validated the system to ensure that the system is releasing drugs properly;
4. The pharmacist in charge monitors an automated pharmacy system for proper use and tests the accuracy of the system at least every 6 months, and whenever any change or upgrade is made to the system;
5. Timely and documented maintenance is performed on the dispensing machine and all other components of an automated pharmacy system in accordance with the manufacturer's recommendations;
6. The purity, potency, and integrity of the drugs contained in the automated pharmacy system is preserved;
7. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules;
8. In the event of a consumer-level recall, the pharmacist in charge can access records of all drugs that have been secured in the automated pharmacy system;
9. The pharmacist in charge develops and maintains a comprehensive backup strategy and disaster recovery plan for use in the event of a technical malfunction resulting from loss of power or internet connectivity or a system malfunction; and
10. Requirements for controlled substances security are met.

STATUTORY AUTHORITY: 32 M.R.S.A. §§13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

EFFECTIVE DATE:

November 8, 2004 - filing 2004-522